NIH POLICY MANUAL

54512 - SUMMARY STATEMENTS
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A. Purpose:

This chapter specifies content, format, disposition, and amendment procedures for summary statements describing Initial Review Groups' (IRGs) considerations of grant and cooperative agreement applications, hereafter both referred to as grant applications. It establishes uniform guidelines for summary statements conveying recommendations of the IRGs to the Bureaus, Institutes, and Divisions (BIDs) and their Councils and Boards.

B. Applicability:

These guidelines are applicable to summary statements for all competing grant applications. The guidelines are necessarily general, intended to allow for adaptation to the unique features of the grant mechanisms and the program requirements of the BIDs.

C. References:

NIH Manual Chapters:

1. 4107 - Review of Applications and Award of Grants Involving Human Subjects.
2. 4108 -Grant and Cooperative Agreement Applications Involving the Biological Effects of Ionizing Radiation.
3. 4206 - Responsibility for Care and Use of Animals
4. 4510 - Referral and Initial Review of NIH Grant and Cooperative Agreement Applications
5. 4511 - Project Site Visits Involving Review of Grant and Cooperative Agreement Applications
6. 4513 - Review of NIH Programs and Grant and Cooperative Agreement Applications by National Advisory Councils and

Boards

7. 4514 - Role of Staff at Advisory Committee Meetings and Exchange of Information Between Initial Review Groups and Bureaus, Institutes, and Divisions

8. 4516 - Principal Investigator Generated Communications and Appeals to Referral and Peer Review of NIH Grant and Cooperative Agreement Applications (In preparation)

D. Definitions:

1. Administrative note An addendum to the summary statement pertaining to aspects of an application other than scientific or technical merit which the IRG or Executive Secretary considers important enough to be brought to the attention of the BID and Council.

2. Amendment A correction, deletion, addition, or other revision of the record(s).

3. Applicant Any institution requesting a grant. In certain instances a principal investigator may apply as an individual and be considered the applicant.

4. Candidate An individual in whose behalf a developmental award or fellowship is requested.

5. Communication A written request for amendment of the record(s) and/or rebuttal letter. Oral communications must be confirmed in writing.

6. Council/Board The National Advisory Council or Board (hereafter called "Council" which has responsibility for the second level of review and recommendation of applications for assistance support.

7. Executive Secretary NIH scientist administrator, either in DRG or BID, who is responsible for implementation of the initial review process for applications.

8. Freedom of Information Coordinator NIH staff member who provides general advice to staff on implementation of the Freedom of Information Act, ensuring that policies and procedures relating to requests for information are consistent with requirements of the Act.

9. Hazardous materials Those materials that may upon exposure be likely to cause damage to the environment or human health.

10. Initial Review Group A group of primarily non-Federal scientific

experts which evaluates the scientific and technical merit of assistance applications.

11. Principal Investigator or Program Director A qualified individual designated by the applicant institution to provide the scientific direction of the assistance activity.

12. Privacy Act Coordinator NIH staff member who provides general advice to DRG or BID staff on implementation of the Privacy Act, ensuring that policies and procedures are consistent with requirements of the Privacy Act and related documents.

13. Record Any information about an individual, maintained by NIH, and identifiable by the individual's name or other unique identification associated with the individual.

E. Policy:

The summary statement shall be the official NIH record and transmittal document for recommendations made by an IRG to a National Advisory Council regarding a specific request for support.

The Executive Secretary of the IRG shall prepare a summary statement for each application reviewed. The summary statement is based on the written comments submitted by assigned reviewers, the gist of the discussion that took place at the meeting, and rationale for the recommendations. It represents the IRG evaluation of the application and documents the salient features of the group deliberations and recommendations. Summary statements are routinely sent to the principal investigator, program director, or candidate by the BID after completion of the review process. Summary statements (without priority score) will be provided by the BID to only the principal investigator, program director, or candidate upon written request in the interim between the meeting of the IRG and the Council.

The BID, for particular programs, may add to but may not subtract from the basic minimum standards set forth in this issuance.

F. Uses of Summary Statements:

Council members use summary statements as the main source of information about applications and as the primary basis for their recommendations.

Institute staff use summary statements as guides in the management of the resulting grants and when discussing with investigators certain BID actions.

Summary statements call to the attention of Council and staff any concerns about adequacy of assurances and information on research proposed to involve human subjects or vertebrate animals.

The copy of the summary statement with priority score sent to each principal investigator following Council is important to the investigator in reassessing, adjusting, or improving his or her research project, as well as in preparing future applications.

Summary statements can provide background information to future reviewers and advisory committees regarding a revised, supplemental, or competing continuation application.

Staff members of committees of the Executive Branch or of Congress may use summary statements in the course of their studies of the NIH.

Summary statements are valuable sources of information for use by NIH staff when recruiting for membership on review and advisory committees.

G. Implementation:

1. Format and Content

a. All summary statements should include certain general features; these may be modified as appropriate for specific grant mechanisms. Common elements for all summary statements include the following:

(1) Color coding of paper used for printing of summary statements:

R series (and P40s)	pink
P series	salmon
S series	salmon
F series	yellow
K series	blue
T series	green
U series	yellow

(2) Face page, with Heading, Recommendation, Special

Note (where applicable), and Resume

(3) Description of the project or program

(4) Critique

(5) Other considerations as appropriate (under Special Note):

(a) concerns if assurances are inadequate to demonstrate that:

-- due consideration has been given to the rights and welfare of human subjects;

-- due consideration has been given to safety issues related to hazardous materials and procedures;

-- animals used in the proposed research will receive proper care and humane treatment;

(b) matters of administrative concern, such as policy issues or budget overlap, which the IRG or the Executive Secretary consider important enough to bring to the attention of the BID or Council/Board;

(c) in the event of a split vote with two or more dissenting votes, the minority view should follow the majority evaluation;

(6) Rosters of the Initial Review Group and site visitors (when appropriate) with an asterisk denoting special reviewers. A footnote should indicate that no advisors were present during the review of an application if their participation would constitute a conflict of interest.

b. Summary statements for regular research project grant applications (R series) should include the following sections: (If applications are recommended for disapproval, only the Resume, Description, and Critique sections need be included unless other sections are particularly relevant to the disapproval recommendation.)

(1) Face Page (Appendix 1)

(a) Heading
(b) Recommendations

(c) Special Note (where applicable)
(d) Resume: A brief summary should describe the proposed project and the major strengths and weaknesses upon which the recommendation and priority score are based.

(2) Body

(a) Description: The objectives and procedures of the proposed research should be concisely described. Summary statements for competing continuation, supplemental, or amended applications should include a description of the background, significant events, and substantive changes.

(b) Critique: This section should present a comprehensive evaluation of the application, including the significance and originality of the proposed study in its scientific field, the validity of the hypothesis, the logic of the aims, and the feasibility and adequacy of the procedures for the proposed research. Both strengths and weaknesses should be addressed to reflect accurately the reviewers' assessment of all critical aspects of th proposal. Care should be taken not to use language which would identify an individual reviewer. Su mary statements for competing continuation and supplementalapplications should include evaluations of past progress. Similarly, summary statements for deferred or amended applications should refer to the previous review.

(c) Investigator: The qualifications of the principal investigator and other key staff to conduct the proposed research should be evaluated, including such factors as academic qualifications, research experience, productivity, and special attributes.

(d) Resources and Environment: If applicable, important aspects of the facilities and equipment should be described and discussed, as well as the extent of departmental and interdepartmental cooperation, and the availability of essential laboratory, clinical, animal, computer, or other resources.

(e) Budget: This narrative section should establish whether all items of the requested budget (initial period and each future year) are considered realistic and justified in terms of the aims and methods of the research. Reasons for each recommended modification in amount or duration of support must be presented.

(f) Administrative Note: Optional. This note may be used when the Executive Secretary wishes to bring to the attention of the BID any matter not concerned with scientific or technical merit.

(g) Human Subjects and Animal Welfare: This section should be used when it is necessary to describe IRG concerns about the adequacy of the plans in the proposed research for protection of human subjects and humane care and treatment of animals.

(h) IRG Roster: (See G.1.a. (6))

c. Summary Statements for multiproject research grant applications (M, P, and S series) should include the following:

(1) Face Page (Appendix 1)

(a) Heading
(b) Recommendation
(c) Special Note (where applicable)
(d) Resume: A brief summary describing the proposed program and the major strengths and weaknesses upon which the recommendation and assigned priority score are based.

(2) Table of contents (if applicable)

(3) Body

(a) Background: Where appropriate, this section should provide background on developments resulting in submission of the proposal, including grant history for a supplemental, competing continuation, or amended application.

(b) Description: The research focus and long-range goals of the program should be briefly described. The chief studies and disciplines involved in the

application and status, importance, and prospects for research should also be included. The relation of the program to other activities in the institution (such as other related research projects) and the extent of institutional, departmental, and interdepartmental cooperation should be discussed.

(c) Principal Investigator: The background and accomplishments of the principal investigator, or program director, including an appraisal of his or her ability and commitment to assume scientific and administrative leadership of the program should be addressed.

(d) Program Administration: The administrative relationships of the proposed program to the institution should be described and, as appropriate, evaluated. Issues relating to institutional commitment and settings are relevant. The mechanisms should be described to ensure the coherence of the project and maintain a multidisciplinary focus. An indication should be given of how, and to what extent, advisory groups will be used. The fiscal strength, stability, and responsibility of the institution, as well as its arrangements for fiscal management of the requested grant funds, should be evaluated.

(e) Support to be Negotiated for Replacement: All active and pending support to be replaced if the application is funded should be noted. Any areas of overlap should be specifically described to assist the BID staff in negotiating a final award.

(f) Program Expansion: For competing continuation and supplemental grant applications, a report covering program expansion should provide a broad overview and evaluation of the major scientific and fiscal factors which are responsible for the differences between current and requested budget costs in the new application.

(g) Individual Sub-project Components: There should be a report evaluating each of the individual research sub-projects and core components that constitute the program. The report for each of thes projects and cores should begin with the number of

the sub-project or core, its title, and the name of the responsible investigator(s). Each report should include the following sections.

(i) Description: A concise description should be prepared, including aims and procedures of the proposed project or core. The background is also described, if appropriate, in cases such as a competing continuation, supplemental, or amended application.

(ii) Critique: The strengths and weaknesses of various aspects of the sub-project should be presented assessing the merit of plans for the future and, where appropriate commenting on past progress. This section should reflect the consensus of the group, based on the BID's stated review criteria for grants under various mechanisms and programs.

(iii) Investigators: The qualifications of the professional staff who will participate in the project should be evaluated with an assessment of their past achievements, their contribution to the proposed program, their potential for sustained activity and development, and the adequacy of their time commitment. The adequacy of scientific support staff should be addressed. Names of particular investigators responsible for individual projects should be identified.

(iv) Budget: This narrative section should evaluate the proposed budget and detail any recommended modifications in the requested budget and/or period of support. Adequate justification for these changes must be presented.

(v) Recommendation: The final recommendation of the IRG for the project is presented.

(h) Resources and Environment: If applicable, important aspects of the facilities and equipment

should be described and discussed, as well as the extent of departmental and interdepartmental cooperation, and the availability of essential laboratory, clinical, animal, computer, or other resources.

(i) Budgets: The attached form (Appendix 3) was designed to be used for multiproject research grant applications. The recommended budget, shown by categories for all sub-projects and cores for all years, should be presented. A separate form should be used for each recommended period. If annual escalations are not included, this should be indicated with an asterisk following the figures for each year affected. A summary budget (Appendix 4) should represent the entire recommended program. All budget calculations must reconcile with the budget narrative for each component.

(j) Overall Critique: This section should provide a summary of the total recommended (approved or disapproved) program and rationale for the recommendations. The strengths and weaknesses of the overall program are considered in relation to the stated review criteria.

(k) IRG Roster: (See G.1.(6))

d. Summary Statements for Manpower Development and Training Grant applications (F, K, and T Series) should include the following:

(1) Face Page (Appendix 2)

(a) Heading
(b) Recommendation
(c) Special Note (where applicable)
(d) Resume: A brief narrative summary should describe the principal qualifications of the candidate and/or the merits of the proposed program, the recommendation of the IRG with the reasons for the recommendation and the priority score.

(2) Body

(a) Description of Research Training Proposal and/or Training Development Plan: The objectives of the proposed research training or development

program should be concisely described. Summaries of review of competing continuation or amended applications should include a description of the background, significant events (e.g., project site visit), and substantive changes. There should be neither opinion nor evaluative comments in this section. When appropriate, this section should include the candidate's career goals, the impact of an award on the candidate's training or development, and the nature of institutional commitments to the candidate. For institutional training programs, the general areas of research in which training is to be offered, institutional plans, and availability of trainees should be included.

(b) Candidate or Program Director: When applicable this section should describe and evaluate the academic background, prior professional training, prior research experience, publications, awards and honors, and references. For institutional NRSA awards it should include the program director and participating faculty's experience in research, research training, and administration.

(c) Training Resources and Environment: Important elements of the facilities and equipment should be described and discussed, as well as the extent of departmental, interdepartmental, and interinstitutional cooperation, if applicable. Comments should be made about the availability of course work, essential laboratory, clinical, animal, computer, and other resources, including subject populations. When appropriate, the assessment should also include the qualifications of the sponsor, participating or development faculty, and their relationship to the proposed program.

(d) Past Training Record (T Mechanisms): For institutional awards an assessment of past training should include the numbers of individuals trained, their present positions, and the extent to which they have been involved in research following completion of their training. For competing continuation applications a statement should be made concerning numbers and levels of training positions awarded and filled each year in the preceding project period.

(e) Critique: The scientific and technical review should be summarized and an evaluation of the total program provided. The strengths and weaknesses of the overall program should be presented with respect to the review criteria for the particular program mechanism. The appropriateness of the duration and/or budget should be considered part of the evaluation when relevant.

(f) IRG Roster: (See G.1.a.(6))

2. Summary Statements for IRG Deferred Applications

a. Domestic Deferrals: If action on a domestic application is deferred by the IRG, the Executive Secretary should inform the principal investigator as soon as possible after the IRG meeting in a letter or an interim summary statement (not submitted to a Council for review). This communication should indicate the areas of concern to the IRG and should carefully formulate the questions requiring answers.

b. Foreign Deferrals: If an application from a foreign institution is deferred for a project site visit, a summary statement must be prepared. These circumstances should be noted in the Heading under the Special Note; the Critique should explain the need for a site visit. When necessary, this information will be used by the Council as a basis for its decision about endorsing the need for a project site visit.

3. Disposition, Distribution, and Amendment of Summary Statements

a. Disposition: The summary statement must be transmitted promptly to or within the BID whose Council is responsible for the second level of review. These reports are the main sources of information for Council members; for BID program and grants management staff members in the performance of their duties related to administrative and fiscal decisions; for advice to candidate-investigators concerning responses to rebuttals; for candidate-investigators in reassessing, adjusting, or redesigning their research projects; and for background information provided to subsequent reviewers related to revised, supplemental, or competing continuation applications.

In addition to normal distribution of summary statements by the IRG Executive Secretary, a copy of each summary statement for IRG favorably recommended "P" applications and those "R"

(except R-25) and S06 applications which involve multiprojects shall be forwarded to the Data Processing Section, Statistics and Analysis Branch, DRG, Room 120, Westwood Building.

At the same time the other copies of summary statements are distributed, copies of summary statements for all applications proposing research involving the use of human subjects, whether recommended for approval or disapproval, shall be sent to the Office for Protection from Research Risks (OPRR) as soon as possible following the IRG meeting. This action is also required if problems are identified in the use of animals for proposed research.

b. Privacy Act Requests Prior to Council: Principal investigators, candidates, and program directors may obtain copies of their summary statements after the IRG meeting and before the normal automatic distribution which follows Council review, by making a written request to the BID program official who, in turn, refers the request to the BID's Privacy Access Official for grants records. Prior to Council review, copies of the summary statement sent to investigators shall have priority scores deleted.

c. Amendment: The Privacy Act requires the NIH to amend a summary statement at the request of the principal investigator if the record is not accurate, relevant, timely, or complete. Matters of expert opinion are not subject to amendment. After initial review, all communications from a principal investigator shall be forwarded to the BID program officials designated by the BID Associate Director for Extramural Programs. If, in the judgment of the BID program official, the information in the communication may result in the summary statement being amended or in the application being deferred, the IRG Executive Secretary should be consulted. A decision to amend is made by the program official and the Executive Secretary who, in the case of DRG reviews, consults with the appropriate Assistant Chief, SRB, DRG, and in the case of BID reviews, with the BID Review Officer.

When an amendment to information is made in a summary statement, notification of the corrective action is made in all records and to all persons and agencies to whom the summary statement has been made available, except when the disclosure was made 1) under the Freedom of Information Act; or 2) to other HHS agencies. In these two cases notification is not required. When information in the summary statement is corrected, the original information should be retained as a historical record in case it is necessary to document a previous Department action or decision

which affected the individual.

d. Distribution: As soon as possible following Council meetings, the BID will send a copy of the summary statement on all IRG approvals or disapprovals to the principal investigator or progra director ONLY. If there is particularly sensitive information about another individual named in the summary statement, BID staff shall consult the BID Privacy Coordinator for guidance in determining whether such information should be deleted.

Barring such deletions permitted by the Privacy Act, no other deletion from the summary statement shall be made.

On those applications on which a Council takes an action that is different from, or in addition to, that recommended by the IRG, the BID must include, with the summary statement, information indicating the Council decision and the supporting rationale.

H. Effective Date:

This policy is effective on date of release.

I. Additional Information:

For further information on this manual chapter, contact, Office of Extramural Research and Training, OD, 496-2241 or Division of Research Grants, 496-7248

J. Additional Copies:

For copies of this manual chapter send a form NIH 414-5, "Request for Manual Chapter" to the Printing and Reproduction Branch (P&RB), DAS, Building 31, Room B3BE07; or call the Office of Extramural Research and Training, 496-5967.

Refer to Hardcopy Appendix 1
Refer to Hardcopy Appendix 2
Refer to Hardcopy Appendix 3
Refer to Hardcopy Appendix 4